NORTH AMERICAN NEUROMODULATION SOCIETY

8735 W. Higgins Road | Suite #300 | Chicago, IL 60631

Email: info@neuromodulation.org | **Phone:** 847.375.4714 | **Fax:** 874.375.6492

www.neuromodulation.org

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Dear Blue Cross Blue Shield of Illinois,

On behalf of the more than 1,700 members of the North American Neuromodulation Society (NANS), we appreciate the opportunity to comments on the recent BCBS policy SUR712.009.

We are specifically disturbed by what we feel is the inappropriate characterization of closed loop spinal cord stimulation (SCS) therapy as "experimental, investigational, and/or unproven."

NANS is a multi-specialty association dedicated to the development and promotion of the highest standards for the field of neuromodulation. Our membership consists of neurosurgeons, orthopedic spine surgeons, anesthesiologists, physiatrists, psychologists, urologists, and neurologists, engineers and other scientists, all dedicated to improving the care our patients receive when dealing with chronic neurologic disorders.

In particular, we are alarmed by the misidentification in the Blue Cross Blue Shield of Illinois policy of closed-loop SCS therapy as "experimental, investigational, and/or unproven." In fact, this specific system has been studied in high-level studies, including randomized, blinded clinical trials. These show strong outcome data with significant improvements in pain , function, mood, sleep and quality of life in patients with back and leg pain with two year follow-up (Evoke study). The benefits from close- loop SCS allowed a significant number of patients in both the Evoke and Avalon studies to titrate off opioid therapy.

This level of scientific evidence and multiple peer reviewed publications is clearly at odds with the BCBS policy's characterization of closed loop SCS therapy as "experimental, investigational, and/or unproven."

Moreover, the Evoke Closed-Loop Spinal Cord Stimulation system has received a Transitional-pass-through (TPT) designation from CMS to facilitate the adoption of this technology. As you know, systems that receive TPT must provide "substantial clinical improvement" and therefore demonstrates that the device or treatment "significantly improves clinical outcomes for a patient population as compared to currently available treatments."

In reading the draft policy, the main criticism of the scientific evidence is the use of the same device in both the open loop and closed-loop arms in the Evoke clinical trial. The policy states that because of this, it "may not be considered a true comparative analysis of open-loop vs. closed-loop systems." This is incorrect, as the use of a single device in this instance allows a true comparison between the current technology (open-loop) and the technological advancement (closed-loop stimulation) while being able to blind the patient to the stimulation modality used. This makes the study methodology stronger than if the patient knew they were receiving either a newer device or one that was already on the market, which would unblind the patient, and possibly the evaluator. Importantly, open-loop stimulation used

here is the same stimulation waveform delivered by all other SCS systems currently on the market, making this trial one comparing a standard of care stimulation paradigm to a novel paradigm. The quality of this study and the results have been subjected to rigorous peer review and published in both *The Lancet* and the *Journal of the American Medical Association* (JAMA), two quality journals with exceptional standards and high impact factors.

The draft policy also suggests other limitations. Specifically, "larger multicenter RCTs that compare Evoke with other SCS devices or other treatment modalities and report on long-term (>5 year) patient-oriented outcomes are needed." The efficacy of closed-loop SCS therapy has been studied out to three years of follow up and the have been presented at national meetings, such as the 2023 North American Neuromodulation Society Annual Meeting. The suggestion to force patients wait five years to receive this therapy does not have a basis in the science. Additionally, closed-loop SCS therapy was shown to be at least as good, if not better than open-loop SCS, a treatment modality in use for over 4 decades and well-proven to be superior to multiple conservative treatment modalities as well as repeat spinal surgery.

The suggestion that closed-loop SCS therapy must be studied against "other treatment modalities" overlooks years of high-level peer-reviewed published evidence as to the efficacy of SCS therapy in improving the quality of life of patients suffering from chronic pain appropriately treat our suffering patients. We request that you reevaluate your conclusions, taking into account the full body of scientific literature on SCS.

The field of neuromodulation, including NANS and its members, recognizes the technological advancement and improved value of closed-loop spinal cord stimulation. For the first time we have the ability to deliver electricity to the spinal cord, measure the physiologic response to that stimulation, and automatically respond to it, providing patients with truly individualized care. Labeling closed-loop SCS as "experimental, investigational, and/or unproven" is exceedingly inaccurate. This technological advancement is a tremendous step forward for the benefit of our patients suffering from chronic pain. Patient access to this scientifically validated advancement should not be limited.

The North American Neuromodulation Society strongly urges you to reconsider your position on closed-loop SCS therapy.

Written and signed on behalf of the 1,700 members of NANS.

Regards,

Julie Pilitsis, MD, PhD
President, North American Neuromodulation Society, Board of Directors
Dean of The Charles E. Schmidt College of Medicine
Florida Atlantic University
Boca Raton, FL

Corey Hunter, MD
President-Elect, North American Neuromodulation Society, Board of Directors
Founder
Ainsworth Institute
New York, NY

David Provenzano, MD
Co-Chair, North American Neuromodulation Society, Advocacy Committee
President
Pain Diagnostics and Interventional Care
Sewickley, PA

Joshua Rosenow, MD
Co-Chair, North American Neuromodulation Society, Advocacy Committee
Professor of Neurosurgery, Neurology and Physical Medicine and Rehabilitation
Northwestern University Feinberg School of Medicine
Chicago, IL

Jonathan M. Hagedorn, MD
Co-Chair, North American Neuromodulation Society, Guidelines Committee
Assistant Professor of Anesthesiology and Perioperative Medicine
Mayo Clinic, Rochester, MN

David Dickerson, MD
Co-Chair, North American Neuromodulation Society, Guidelines Committee
Assistant Professor of Anesthesia and Critical Care
University of Chicago Medicine
Chicago, IL

Ahmed Raslan, MD
Adviser, North American Neuromodulation Society, Guidelines Committee
Associate Professor of Neurological Surgery
Oregon Health & Science University
Portland, OR

Samir J. Sheth, MD
Chair, North American Neuromodulation Society, Spinal Cord Stimulation Subcommittee
Sutter Medical Group, Sutter Health Systems
Sacramento, CA

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